K020396

APR 1 0 2002

510 (k) SUMMARY

SUBMITTED BY:

M. K. Patterson, Jr. PhD
Sr Vice President
Regulatory Affairs
IMTEC Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

(580) 223-4456

F.D.A Registration Number: 1645158
Owner / Operator Number: 9003407

Date Submitted: January 30,2002

CLASSIFICATION/COMMON OR USUAL NAME/ DEVICE NAME:

Classification Name: Unclassified Device.
Code:LYC
Common/ Usual Name:GTR
Proprietary Name: BioCELLECT™-perio.

PREDICATE DEVICE:

Epi-Guide™ (K940643)

DEVICE DESCRIPTION:

BioCELLECT™ is composed of a porous structure of synthetic bioabsorbale compressed L (-)Glycolide homopolymer fibers. The porous structure is designed to attach to surrounding soft tissue and inhibit epithelial migration during wound healing. It is a biocompatible, cell occlusive, clinically manageable device that allows for tissue integration without further surgical intervention.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2002

Mr. K. Patterson
Senior Vice President
IMTEC, Corporation
2401 North Commerce
Ardmore, Oklahoma 73401

Re: K020396
Trade/Device Name: BioCELLECT™- perio
Regulation Number: None
Regulation Name: GTR Barrier
Regulatory Class: Unclassified
Product Code: LYC
Dated: January 30, 2002
Received: February 6, 2002

Dear Mr. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020396

Device Name: **BioCELLECT™ -perio**

Indications For Use:

BioCELLECT™-perio is a bioabsorbable implantable membrane intended for use in the surgical management and treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures. It is also used as a membrane that provides a stable barrier for the containment of bone graft material. Its composition allows a relative short term resorption.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrance of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020396